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GRANT NO: DAMD17-93-J-3012

TITLE: CLINICAL EVALUATION OF A DIGITAL MAMMOGRAPHY BASED ON MICRO-LITHOGRAPHY (BREAST CANCER)

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REPORT DATE: March 7, 1995

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick
Frederick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	March 7,1995	Annual 12/1/93 - 11/30/94

4. TITLE AND SUBTITLE

Clinical Evaluation of a Digital Mammography
Based on Micro-Lithography (Breast Cancer)

5. FUNDING NUMBERS

Grant No.

DAMD17-93-J-3012

6. AUTHOR(S)

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Georgetown University
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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

US Army Medical Research and Materiel Command
Fort Detrick
Frederick, MD 21702-5012

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

Collaboration with 3M Corporation

12a. DISTRIBUTION/AVAILABILITY STATEMENT

Approved for public release; distribution unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 words)*

A new digital prototype, developed by 3M Imaging Systems based on a novel photo-conductor sensor has been installed at Georgetown University for technical and clinical evaluation. The detector system has a multilayer structure containing a photo-conductor. The latent image produced by an x-ray is stored on the photo-conductor surface, and is then read out by scanning with a high intensity laser beam. The system has both a wider dynamic range (i.e., 2 to 3 order of magnitude) and spatial resolution compared to conventional screen-film and digital systems.

Before conducting the clinical study, the physical characteristics of the system were studied on phantom images for image quality and radiation dose. The evaluation of the 3M system was divided into two parts: (1) system performance for different kVp and mAs, and (2) system optimization for minimum patient dose. The performance of the system was tested on the body part images that are less radio-sensitive than breast images (i.e., extremities). The performance of the system was improved mainly by redesigning the detector structure and using different image processing parameter settings. By the completion of the second year study, the radiation exposure was optimized and the image quality was improved significantly.

14. SUBJECT TERMS

System Performance and System Optimization

15. NUMBER OF PAGES

31

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

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TABLE OF CONTENTS

1.0 INTRODUCTION	3
2.0 METHODS	5
2.1 IMAGE OPTIMIZATION PROCEDURES	5
2.1.1 PHYSICS EXPERIMENT	5
2.1.2 COMPARISON WITH SCREEN-FILM MAMMOGRAPHY SYSTEM	5
3.0 RESULTS	7
3.1 PART I: SYSTEM PERFORMANCE IN HIGH KVP	7
3.2 PART II: SYSTEM OPTIMIZATION	9
3.2.1 PHANTOM SELECTION(s) AND STANDARD TECHNIQUE(s)	10
3.2.2 SANDWICH TEST	10
3.2.3 CASSETTE/IMAGING PLATE COMBINATIONS	11
3.2.4 ANATOMY/CASSETTE/IMAGING PLATE COMBINATION	15
4.0 DISCUSSION	19
4.1 DISCUSSION OF PART I	19
4.2 DISCUSSION OF PART II	20
5.0 CONCLUSIONS	25
5.1 CONCLUSIONS OF PART I	25
5.2 CONCLUSIONS OF PART II	26
5.3 FUTURE WORK	27
6.0 REFERENCES	28

Principal Investigator: Seong K. Mun, PhD

1.0 INTRODUCTION

The overall goal of mammography is to reduce mortality by the detecting of breast cancer at the earliest possible stage. The incidence of breast cancer is increasing. Each year more than 182,000 women will be diagnosed with breast cancer and 46,000 die of breast cancer in the United States of America.[1] Breast cancer is a major health problem in the U.S. and is the second most frequent cause of cancer death among women after lung cancer.[2,3,4] Unlike lung cancer, however, the causes of breast cancer have not been identified, and until then, a methodology for preventing and curing breast cancer remains unknown.

X-ray mammography is acknowledged to be the most sensitive and specific technique for detecting breast cancer in its earliest and most curable stages. Despite its status as the method of choice in breast cancer detection, it is clear that significant improvements in mammographic performance are possible. Kopans and Plewes in a presentation at the National Cancer Institute Concensus Conference "Breast Imaging: State-of-the-Art and Technologies of the Future" stated that "while there is room for continued development with conventional methods, it is believed that advances in digital acquisition and manipulation of breast images represent the most fertile territory for major advances in the x-ray detection and diagnosis of minimal breast cancers."[5]

Small calcifications are one of the earliest and most reliable, although nonspecific, findings of early and minimally invasive breast cancer.[6] Detections of such lesions truly test the ability of the present digital systems in comparison to the conventional screen-film system which has a far lower spatial resolution.[7,8]. Even digitization of conventional mammographic films with fine pixel size (100 x 100 µm) degrades the detectability of microcalcifications. High quality mammography images require excellent spatial resolution in order to detect fine microcalcifications within the breast. At the same time excellent contrast sensitivity is needed for seeing the subtle differences in x-ray attenuation coefficient between normal and malignant tissues.[9]

Up to the present, two commercially available technologies have been used to perform

digital full breast studies: digitization of screen-film images or production of images on the storage phosphor imaging plate developed by Fuji and Agfa. One advantage of digital over screen-film mammography is higher detector quantum efficiency (i.e., DQE associated with film granularity in screen-film mammography). A second advantage of digital mammography is its much higher detector's dynamic range, which would significantly improve information in the image areas exposed to radiation levels significantly lower or higher than the optimal level. Maidment et al.[10] estimate that dynamic ranges of well over three orders of magnitude will be produced in digital mammography. A third major advantage of digital mammography is that it permits consideration of display characteristics independent of the image capture requirements of the system. Additional advantages of digital mammography are related to the fact that direct digital image acquisition greatly facilitates image processing, computer-aided diagnosis, and image transmission.

Both digital and screen-film systems have been improved significantly, but the characteristic of the systems (i.e., spatial resolutions and contrast detectability for detection of microcalcifications) remained the same. Technologies which may produce digital detectors with both a higher resolution and a field of view needed for mammography are now in the development stage. 3M Corporation has offered Georgetown University their new technology which we believe has significant advantages compared to the existing conventional and digital technologies. This new system has both a wider dynamic range and a higher spatial resolution than the conventional screen-film, storage phosphor, or film digitizer systems.

The new digital system developed by 3M[11,12], uses a novel detector system based on a multilayer structure containing a photo-conductor sensor. The latent image produced at the photo-conductor surface is then read out by scanning the plate with a laser beam. After the laser read out, the image will be processed digitally. The resulting image will be processed and viewed as a soft copy display or a hard copy film as needed. The prototype device operates with a wide dynamic range and produces linear x-ray signal response for clinically reasonable x-ray exposure. Clinical image quality can be obtained at x-ray exposures that are comparable to those used in a conventional screen-film system.

Before conducting the clinical study in a mammography energy range, the system was evaluated for imaging body parts which are less radio-sensitive than breast images. At this phase, the concentration was on the study of phantom such as extremities, the hip, and the shoulder. The physical characteristics of the system such as image quality and radiation dose were studied. In the current evaluation the radiation dose was optimized for extremities and the system was improved significantly, mainly by redesigning the detector and using image processing to enhance the

contrast and spatial frequency for better image quality. The evaluation was divided into two parts. In the first part, the performance of the system was evaluated in high kVp on the study of extremities, hip and shoulder. In the second part, system optimization was performed in order to minimize the patient dose on the extremities.

2.0 METHODS

The 3M imaging system is a new technology that has not yet been established as suitable for clinical mammography examination. Therefore, a sequence of experiments was performed to study the system's physical characteristics, image quality, and image sensitivity. The study also includes radiation dose optimization for good image quality. The experiments were performed on body parts that are less radio-sensitive than breast. The physical characteristics of the system such as image quality and radiation dose were studied in a energy range higher than mammography energy range.

2.1 IMAGE OPTIMIZATION PROCEDURES

2.1.1 PHYSICS EXPERIMENT

A series of tests were performed to optimize the system's performance for kVp and mAs on the system's image quality. The tests concentrated on the images of the extremities, the hip, and the shoulder for a range of mAs and kVp.

The optimization procedures are based on physics (geometric) phantoms and anthropomorphic phantoms. The tests include the following:

a- Exposure technique(s). This is utilized to optimize the kVp, mAs, and some machine specific parameters involved in the optimization.

b- Image processing. This is utilized to optimize image processing (i.e., contrast enhancement and spatial frequency enhancement using different noise reduction filtering).

2.1.2 COMPARISON WITH SCREEN-FILM MAMMOGRAPHY SYSTEM

The 3M digital system's overall performance was compared with those of the conventional screen-film system. Typically, an imaging system should have a high spatial resolution, relatively high contrast, and low noise. The overall system image quality was conducted using a series of test phantoms. Given the range of kVp and mAs (as obtained from the optimization procedure

described above) given for extremities, hip, and shoulder, we have placed the test phantoms and experimentally conducted several quantitative measures. The study include the following:

- **a. Noise characteristics**
- **b. Contrast**
- **c. Spatial resolution**
- **d. Potential image artifact**

3.0 RESULTS

In order to evaluate the 3M imaging system in a clinical environment in a mammography energy range, the feasibility of the system was studied for images of the body parts that are less radio-sensitive than breast images. The feasibility of the system was evaluated for physical characteristics, system image quality, as well as the radiation dose requirement. The evaluation was divided into two parts:

3.1 PART I: SYSTEM PERFORMANCE IN HIGH KVP

In the first part of the evaluation of the 3M system, the clinical feasibility was studied in high kVp. The focus was on the imaging of extremities, the hip, and the shoulder. The results were compared with those from the conventional screen-film (SF) system.

Fuji GF-1/HR-G (50 speed) film was used for extremities exams and Fuji GH-1/HR-G (400 speed) film was used for the shoulder and the hip exams. The high resolution scanning technique and standard resolution scanning technique were used for the 3M system.

The exam rooms at Georgetown University Hospital were tested using the dosimeter for consistency of X-ray exposure. The Radcal Model 9010MS Radiation Monitor with 90x5-6M and 90x5-180 ion chambers was used for dose measurement. The entrance dose was measured for the primary beam at the center of the phantoms. The exposure results are consistent for different kVp and mAs. These results are listed in Table 3.1 and are plotted in Figure 3.1.

Table 3.1 Average dose for different values of kVp and mAs, measured for primary radiation.

mAs	mR (40 kVp)	mR (50 kVp)	mR (60 kVP)
2.0	2.3	4.3	6.8
2.5	2.8	5.5	8.7
3.2	3.4	6.7	10.6
4.0	4.3	8.5	13.3
5.0	5.4	10.5	16.9
6.3	6.7	13.2	21.0
8.0	8.5	16.6	26.6
10.0	10.7	20.8	33.4

Note : SDD = Source to Detector Distance = 40",
Small Focal Spot Size, No Added Filtration

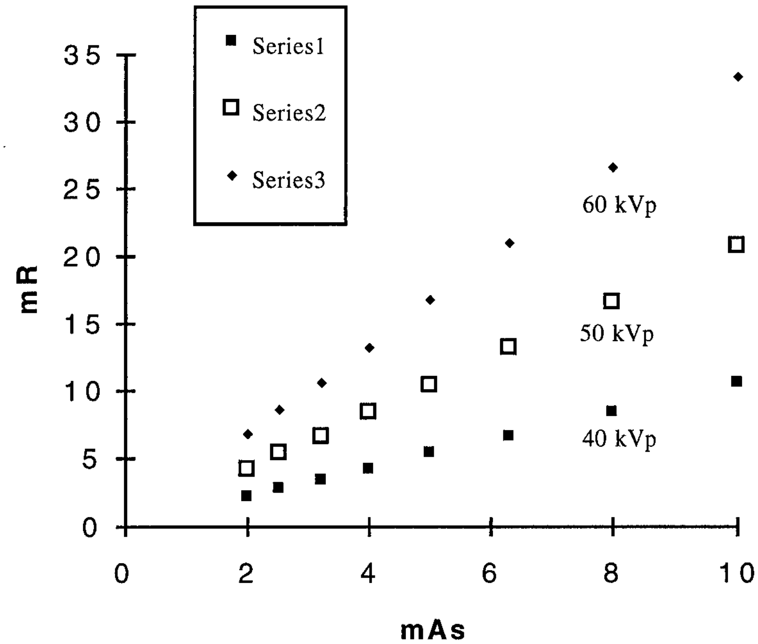

Figure 3.1. Average dose for different values of kVp and mAs.

In part I, the test was performed on the following phantoms:

- a- **Hand Phantom**
- b- **Foot Phantom**
- c- **Lateral Foot (AP)**
- d- **Hip from Pelvis Phantom**
- e- **Shoulder from Chest Phantom**

Two physics phantoms were also used to study 3M images for resolution and sharpness:

- f- **Line Pair / Resolution Phantom** (Nuclear Associates 07-525) (3.15 - 16.6 lp/mm)
- g- **Step-wedge Phantom (14 Steps and 10 Steps Aluminum)**

The experiments were performed for a range of kVp and mAs depending on the 3M system application. Several exposures were used for 3M system's image optimization in comparison with the screen-film system. Source Detector Distance (SDD) was fixed at 40 inches. For hip and shoulder studies the grid was used for scatter radiation reduction. The exposures were fixed for the screen-film, but varied for the 3M system in the preliminary image optimization. The techniques used for the initial phase are listed in Tables 3.2 and 3.3.

Table 3.2 Standard Techniques For Different Anatomical Regions

Anatomy	kVp	mA	sec.	mAs	SDD	Bucky	Tabletop	AFS(large)	AFS(small)
Hand (Ext. Cassette)	60	250	.02	5	40"		x		x
Foot (Ext. Cassette)	63	250	.02	5	40"		x		x
Foot (LAT) (Ext. Cassette)	63	250	.02	5	40"		x		x
Shoulder (From Chest)	70	250	.04	10	40"	x			x
Hip (From Pelvis))	70	250	.04	10	40"	x			x

Note : STANDARD TECHNIQUE REFERS TO THE ONE USED IN SCREEN-FILM RADIOGRAPHY.
SDD Source to Detector Distance
AFS Focal Spot Size

Table 3.3 Techniques For Physics Test

Phantom	kVp	mA	sec.	mAs	SDD	Bucky	Tabletop	AFS(large)	AFS(small)
Step-wedge	70			2	40		x	x	
Step-wedge	70			10	40		x	x	
Line pair / Resolution	40			1.2	40		x		x
Line pair / Resolution	50			2.5	40		x		x

Note : SDD Source to Detector Distance,
AFS Focal Spot Size

All of the images taken from the 3M and SF systems were compared and evaluated in order to determine whether or not to proceed to clinical studies.

3.2 PART II: SYSTEM OPTIMIZATION

In part II of the evaluation, the system optimization was performed on the imaging of the extremities. The focus was on finding the optimum technique(s) to apply to the anatomy, specifically the hand and foot, for the best image quality in terms of kVp, mA, and exposure time as well as the exposure dose (mR). The results were submitted to the Institutional Review Board (IRB) for clinical trial for extremities. Clinical study was subsequently approved. Sandwich tests were performed on the 3M imaging system in order to measure the skin dose and absorbed patient

dose in the combinations of the anatomy/cassette/imaging plate. The sensitivity of the system was studied on the image quality and the exposure dose, by systematically and consistently varying kVp, mA, and exposure time. The comparison of the results are given in section 3.2.3.

3.2.1 PHANTOM SELECTION(s) AND STANDARD TECHNIQUE(s)

In this experiment, the test was performed on the following phantoms:

a- **Hand Phantom**

b- **Foot Phantom**

The following physics phantoms were also used to study 3M images for resolution and sharpness:

c- **Line Pair / Resolution Phantom** (Nuclear Associates 07-525) (3.15 - 16.6 lp/mm)

d- **Step-wedge Phantom (14 Steps and 10 Steps Aluminum)**

The experiments were performed for a range of kVp, mA, and exposure time, depending on the application of the individual anatomy. Several exposures were used for the 3M imaging system in order to optimize the image for comparison to screen-film system. SDD is fixed to be 40 inches (102 cm). The exposures were fixed for the SF system, but vary for the 3M system for preliminary image optimization. The standard techniques used for screen-film system are applied in part II are similar to part I of the study, and were listed in Tables 3.2 and 3.3.

In part II of the 3M system evaluation, kVp, mA, and exposure time were varied individually for extremities such as hand and foot. The effect of each variable was recorded and the mR was measured. The images are compared and evaluated for the optimum technique. In this study we would like to use basic image processing parameters available to the machine to see how well the front end device (cassette/imaging plate combination) performs and then use more advanced image processing to improve the image quality of the system.

3.2.2 SANDWICH TEST

To optimize the exposure technique (e.g., kVp, mA, ms, mAs, and mR), a series of experiments were performed to study the effect of each parameter on the 3M system's images. This was done by varying the individual parameters such as kVp, mA, and exposure time as well as the combination of these parameters. The experiments were divided into two categories: one for cassette/imaging plate combination, the other for anatomy/cassette/imaging plate combinations. For

each exam the dosimeter was used to read the mR at different layers of the combination.

3.2.3 CASSETTE/IMAGING PLATE COMBINATIONS

3.a- Incident Exposure Dose Measurement (Skin Dose)

In this study, the dosimeter was attached to the front face of the cassette for measurement. The kVp, mA, and exposure time were modified systematically for each variable. The incident mR was measured. This configuration is shown schematically in Figure 3.2 below.

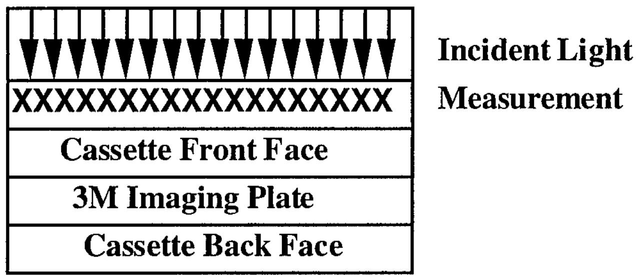

Figure 3.2 Diagram of cassette/imaging plate combinations

The results of the measurement are listed in Tables 3.4 thru 3.7.

Table 3.4 X-ray tube voltage (kVp) variation

Tube Voltage [kVp]	Tube Current [mA]	Time [sec]	Exposure [mAs]	Exposure [mR]	mR/ mAs	Distance [in/cm]	Table-Top	Focal Spot
55	250	0.02	5	17.7	3.54	40/102	X	Small
60	**250**	**0.02**	**5**	**21.5**	**4.30**	**40/102**	**X**	**Small**
63	**250**	**0.02**	**5**	**24.0**	**4.80**	**40/102**	**X**	**Small**
65	250	0.02	5	24.5	4.98	40/102	X	Small
70	250	0.02	5	28.0	5.60	40/102	X	Small

Table 3.5 Tube current (mA) variation (e.g., HAND exam at kVp=60)

Tube Voltage [kVp]	Tube Current [mA]	Time [sec]	Exposure [mAs]	Exposure [mR]	mR/ mAs	Distance [in/cm]	Table-Top	Focal Spot
60	160	0.02	3.2	12.5	3.91	40/102	X	Small
60	200	0.02	4.0	16.3	4.08	40/102	X	Small
60	**250**	**0.02**	**5.0**	**21.5**	**4.30**	**40/102**	**X**	**Small**
60	320	0.02	6.4	23.7	3.70	40/102	X	Small

Table 3.6 Tube current (mA) variation (e.g., FOOT exam at kVp=63)

Tube Voltage [kVp]	Tube Current [mA]	Time [sec]	Exposure [mAs]	Exposure [mR]	mR/ mAs	Distance [in/cm]	Table-Top	Focal Spot
63	160	0.02	3.2	14.5	3.91	40/102	X	Small
63	200	0.02	4.0	18.4	4.08	40/102	X	Small
63	**250**	**0.02**	**5.0**	**24.0**	**4.80**	**40/102**	**X**	**Small**
63	320	0.02	6.4	27.3	3.70	40/102	X	Small

Table 3.7 Exposure time (sec) variation (e.g., FOOT exam at kVp=63)

Tube Voltage [kVp]	Tube Current [mA]	Time [sec]	Exposure [mAs]	Exposure [mR]	mR/ mAs	Distance [in/cm]	Table-Top	Focal Spot
63	250	0.0125	3.2	14.8	4.66	40/102	X	Small
63	250	0.0160	4.0	18.7	4.67	40/102	X	Small
63	**250**	**0.0200**	**5.0**	**24.0**	**4.80**	**40/102**	**X**	**Small**
63	250	0.0250	6.4	29.4	4.60	40/102	X	Small
63	250	0.0320	8.0	38.2	4.77	40/102	X	Small

Note that in tables, the rows in boldface type are the standard exposure settings used in screen-film system for hand and foot exams.

3.b Exposure Dose Measurement After Passing Through the Cassette Front Face

In this study the dosimeter was attached to the back of the exposure face and the exposure dose (mR) was measured at the level shown by character **XXX**. This examination is shown schematically in Figure 3.3 below.

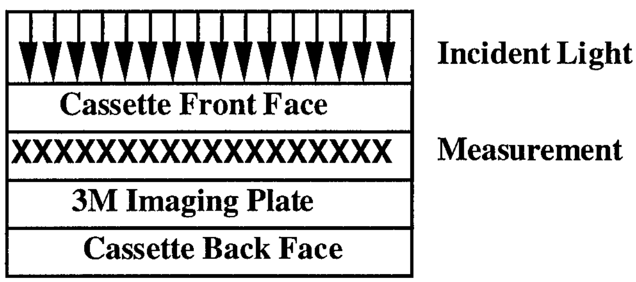

Figure 3.3 Diagram of cassette/imaging plate combinations

The results of this experiment are listed in Tables 3.8 thru 3.11.

Table 3.8 X-Ray tube voltage (kVp) variation

Tube Voltage [kVp]	Tube Current [mA]	Time [sec]	Exposure [mAs]	Exposure [mR]	mR/ mAs	Distance [in/cm]	Table-Top	Focal Spot
55	250	0.02	5	16.4	3.28	40/102	X	Small
60	**250**	**0.02**	**5**	**19.9**	**3.98**	**40/102**	**X**	**Small**
63	**250**	**0.02**	**5**	**22.3**	**4.46**	**40/102**	**X**	**Small**
65	250	0.02	5	23.4	4.68	40/102	X	Small
70	250	0.02	5	26.2	5.25	40/102	X	Small

Table 3.9 Tube current (mA) variation (e.g., HAND exam at kVp=60)

Tube Voltage [kVp]	Tube Current [mA]	Time [sec]	Exposure [mAs]	Exposure [mR]	mR/ mAs	Distance [in/cm]	Table-Top	Focal Spot
60	160	0.02	3.2	11.7	3.66	40/102	X	Small
60	200	0.02	4.0	15.3	3.83	40/102	X	Small
60	**250**	**0.02**	**5.0**	**19.7**	**3.94**	**40/102**	**X**	**Small**
60	320	0.02	6.4	21.9	3.42	40/102	X	Small

Table 3.10 Tube current (mA) variation (e.g., FOOT exam at kVp=63)

Tube Voltage [kVp]	Tube Current [mA]	Time [sec]	Exposure [mAs]	Exposure [mR]	mR/ mAs	Distance [in/cm]	Table-Top	Focal Spot
63	160	0.02	3.2	13.3	3.66	40/102	X	Small
63	200	0.02	4.0	17.0	3.83	40/102	X	Small
63	**250**	**0.02**	**5.0**	**22.3**	**3.94**	**40/102**	**X**	**Small**
63	320	0.02	6.4	25.3	3.42	40/102	X	Small

Table 3.11 Exposure Time (sec) Variation (e.g., FOOT exam at kVp=63)

Tube Voltage [kVp]	Tube Current [mA]	Time [sec]	Exposure [mAs]	Exposure [mR]	mR/ mAs	Distance [in/cm]	Table-Top	Focal Spot
63	250	0.0125	3.2	13.7	4.28	40/102	X	Small
63	250	0.0160	4.0	17.9	4.47	40/102	X	Small
63	**250**	**0.0200**	**5.0**	**24.0**	**4.80**	**40/102**	**X**	**Small**
63	250	0.0250	6.4	28.0	4.40	40/102	X	Small
63	250	0.0320	8.0	36.0	4.50	40/102	X	Small

Note that tables, the bold face rows indicates the standard settings used in screen-film system for hand and foot exams.

3.c Absorbed Dose by the Cassette Front Face

The absorbed dose by the cassette exposure face can be calculated from Tables 3.4 and 3.8. The schematic diagram is shown in Figure 3.4

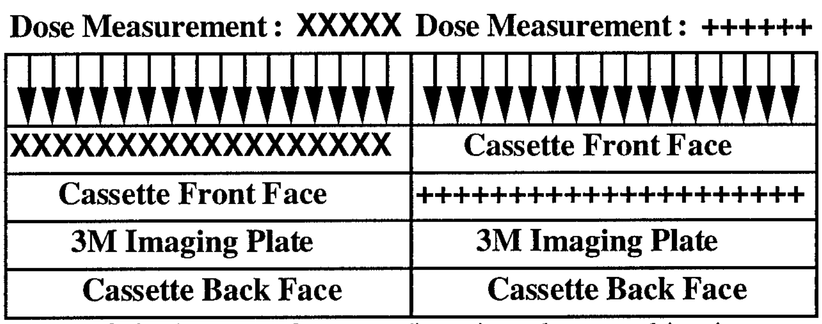

Figure 3.4 Diagram of cassette/imaging plate combination

The results are listed in Tables 3.12 and 3.13, for variation of kVp and mA, respectively.

Table 3.12 Variation of the absorbed dose by the cassette front face as a function of x-ray tube energy (kVp)

Tube Voltage [kVp]	Exposure at (X) [mR]	Exposure at (+) [mR]	Front Face Absorbed Dose [mR]	Front Face Absorbed Dose [mR}
55	17.7	16.4	1.3	7%
60	21.5	19.9	1.6	7%
63	24.0	22.3	1.7	7%
65	24.9	23.4	1.5	6%
70	28.0	26.2	1.8	6%

Note that the experiment was done on tabletop with small focal spot size and at a SDD of 40" (102 cm) with fixed mA=250, exposure time=0.02 sec, and mAs=5.

Table 3.13 Variation of the absorbed dose by the cassette front face as a function of x-ray tube current (mA)

Tube Current [mA]	Exposure at (X) [mR]	Exposure at (+) [mR]	Front Face Absorbed Dose [mR]	Front Face Absorbed Dose [mR}
160	12.5	11.7	0.8	6%
200	16.3	15.3	1.0	6%
250	21.5	19.7	1.8	8%
320	23.7	21.9	1.8	8%

Note that the experiment was done on tabletop with small focal spot size and at a SDD of 40" (102 cm) with fixed kVp=60 and exposure time=0.02 sec.

These results are also plotted in Figures 3.5 and 3.6 as a function of kVp and mA, respectively.

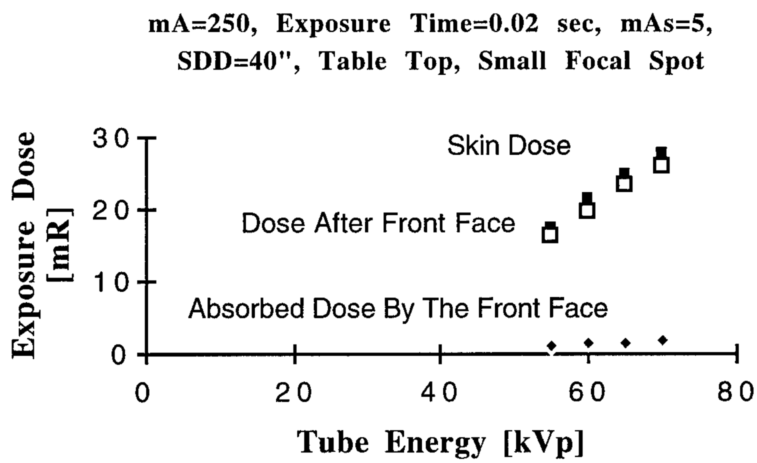

Figure 3.5 Results of absorbed dose for the cassette/imaging plate combination as a function of kVp

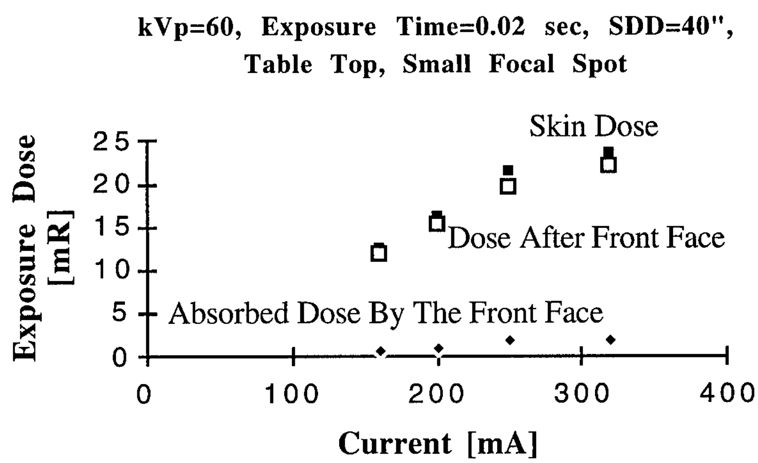

Figure 3.6 Results of absorbed dose for the cassette/imaging plate combination as a function of mA

3.2.4 ANATOMY/CASSETTE/IMAGING PLATE COMBINATION

4.a Exposure Dose Variation as a Function of Tube Energy (kVp) and Tube Current (mA)

In this experiment, kVp and mA were varied individually. We have studied the effect of kVp and mA on the exposure dose given to the patient. The focus was on the study of the extremities (e.g., hand and foot). The exposure dose at different layers of the combination was measured for different sets of kVp and mAs.

HAND EXPERIMENT

In this experiment, the combination of the hand/cassette/imaging plate was exposed and the exposure dose was measured for each combination at different layers as shown in Figure 3.7 by characters (X), (+), and (O).

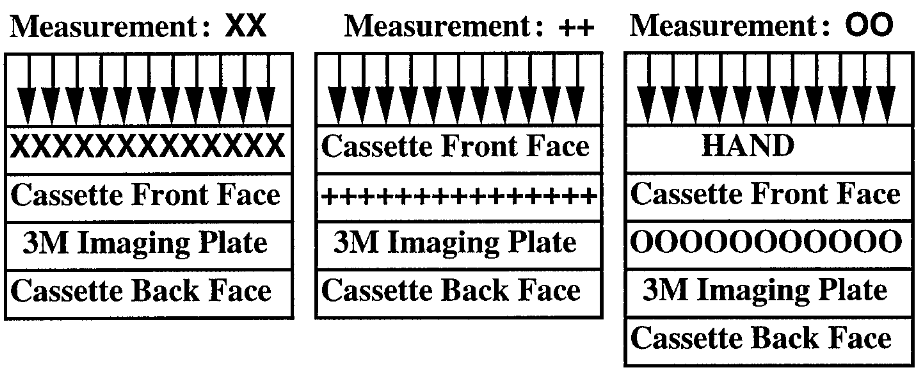

Figure 3.7 Schematic diagram of hand/cassette/imaging plate combinations

The results of this experiment are listed in Tables 3.14 and 3.15, for variation of kVp and mAs, respectively.

Table 3.14 Variation of the absorbed dose by the cassette front face as a function of x-ray tube energy (kVp)

Tube Voltage [kVp]	Exposure at (X) [mR]	Exposure at (+) [mR]	Exposure at (O) Dose [mR]
55	17.7	16.4	5.4
60	21.5	19.9	7.1
65	24.9	23.4	8.6
70	28.0	26.2	10.1

Note that the experiment was done on tabletop with small focal spot size and at a SDD of 40" (102 cm) with fixed mA=250, exposure time=0.02 sec, and mAs=5.

Table 3.15 Variation of the absorbed dose by the cassette front face as a function of x-ray tube current (mA)

Tube Current [mA]	Exposure at (X) [mR]	Exposure at (+) [mR]	Exposure at (O) Dose [mR]	mAs
160	12.5	11.7	4.1	3.2
200	16.3	15.3	5.4	4.0
250	21.5	19.7	6.5	5.0
320	23.7	21.9	7.3	6.4

Note that the experiment was done on tabletop with small focal spot size and at a SDD of 40" (102 cm) with fixed kVp=60 and exposure time=0.02 sec.

These results are also plotted in Figures 3.8 & 3.9 as a function of kVp and mA, respectively.

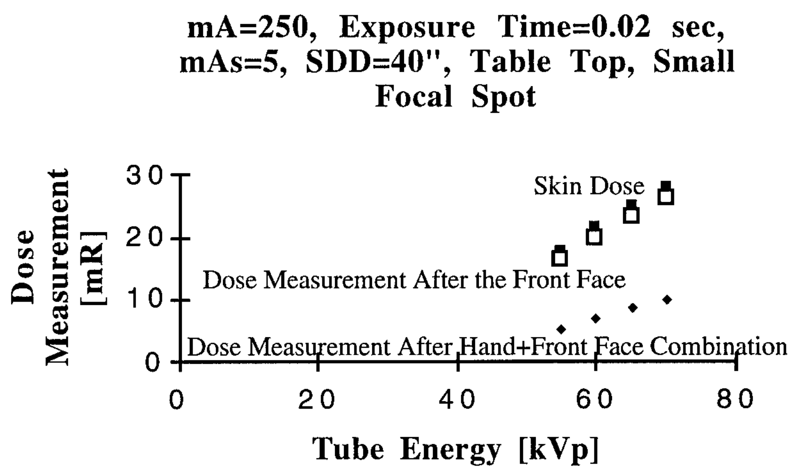

Figure 3.8 Results of absorbed dose for the hand/cassette/imaging plate combination as a function of kVp

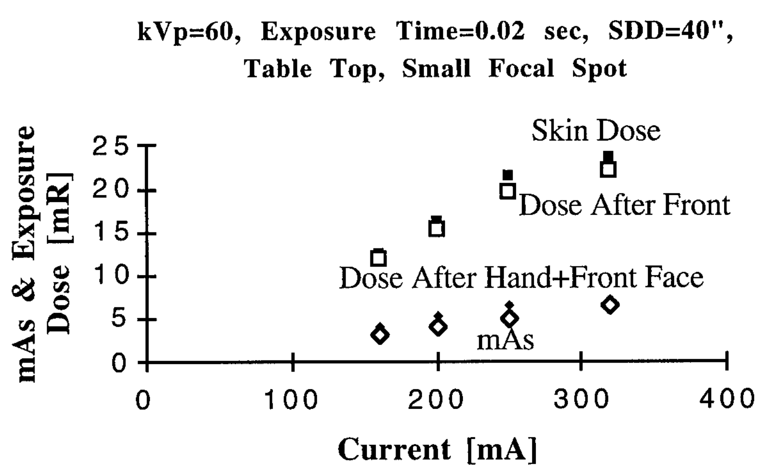

Figure 3.9 Results of absorbed dose for the hand/cassette/imaging plate combination as a function of mA

FOOT EXPERIMENT

In the second experiment, the combination of the foot/cassette/imaging plate was exposed to x-ray and the exposure dose was measured at different layers as shown in Figure 3.10 by characters **(X)**, (+), and **(O)**.

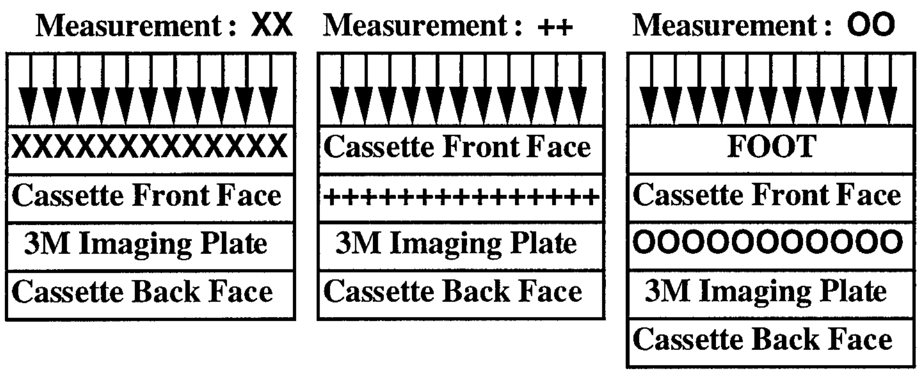

Figure 3.10 Foot/Cassette/Imaging Plate Combinations

The results are listed in Tables 3.16 and 3.17 and are plotted in Figures 3.11 and 3.12.

Table 3.16 Variation of the absorbed dose by the cassette front face as a function of x-ray tube energy (kVp).

Tube Voltage [kVp]	Exposure at (X) [mR]	Exposure at (+) [mR]	Exposure at (O) Dose [mR]
55	17.9	16.4	2.5
60	21.5	20.0	3.6
65	25.2	23.4	4.5
70	28.5	26.6	5.4

Note that the experiment was done on tabletop with small focal spot size and at a SDD of 40" (102 cm) with fixed mA=250, exposure time=0.02 sec, and mAs=5.

Table 3.17 Variation of the absorbed dose by the cassette front face as a function of x-ray tube current (mA).

Tube Current [mA]	Exposure at (X) [mR]	Exposure at (+) [mR]	Exposure at (O) Dose [mR]	mAs
160	14.5	13.3	2.4	3.2
200	18.4	17.0	3.1	4.0
250	24.0	22.3	4.3	5.0
320	27.3	25.3	4.5	6.4

Note that the experiment was done on tabletop with small focal spot size and at a SDD of 40" (102 cm) and with fixed kVp=63 and exposure time=0.02 sec.

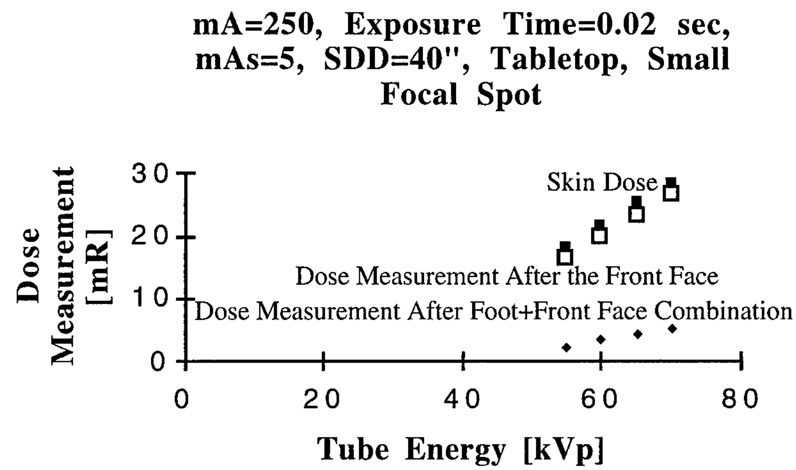

Figure 3.11 Results of absorbed dose for the foot/cassette/imaging plate combination as a function of kVp

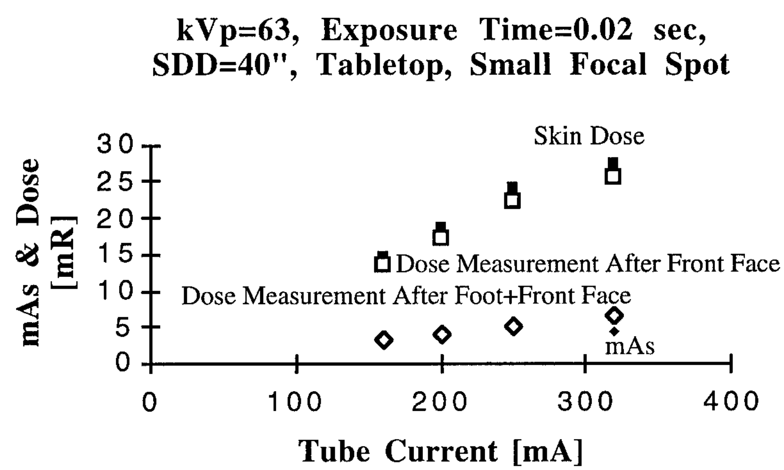

Figure 3.12 Results of absorbed dose for the foot/cassette/imaging plate combination as a function of mA

4.0 DISCUSSION

4.1 DISCUSSION OF PART I

A series of tests were performed on the extremities (hand, foot), the hip, the shoulder, the step-wedge, and the line pair / resolution phantoms in order to evaluate the 3M imaging system's performance in the clinical environment. The optimized (accepted image) images from conventional screen-film (SF) system were compared with the 3M images. Image processing was performed on the 3M images in order to find the preliminary optimum image for comparison with SF images. The images were compared to those taken from SF images and evaluated for clinical studies.

HAND

For the hand study, the 3M image has sufficient resolution compared to SF system but the image is noisy. The conventional techniques used for screen-film images creates vertical lines on the 3M images. The source of this problem is not yet determined. Before we can proceed to clinical study in mammography energy range, the 3M system requires more adjustment. We recommend that more tests be performed perhaps using different settings for kVp and mAs for 3M images.

FOOT

Noise reduction was achieved on the foot exam through image processing capability. In this study the elimination of noise also caused eliminationof the fine structure of the image. As we observed, the noise is more visible on the darker side of the image. The system is going on the right track toward the clinical direction. By eliminating the pattern noise through image processing we have achieved better image quality.

LATERAL FOOT

For this study the image processing was only carried out using contrast enhancement.Two exposure techniques were used in order to optimize the 3M image. The results of this study show that the 3M images are still noisy compared to the images taken from the SF system.

HIP

For the hip study, the pelvis phantom (pediatric) was selected. Three exposures (10, 125, 160 mAs) were used in order to optimize the 3M image. The 3M images require a higher exposure setting than SF system for reduction of the noisy pattern. At a high exposure (4 to 8 times higher exposure compared to the SF system) the 3M system performs very well and produces acceptable quality images. Raising the exposure, on the other hand, creates the elimination of parts of the anatomy on the 3M image. The recommendation is that a pre-scanning of the 3M acqusition device

for read-out might help to reduce the noise on the image and preserve the complete anatomy.

SHOULDER

For the study of shoulder, the chest phantom was used. This exam also used three exposures for optimization of the 3M images at 10, 80, and 160 mAs. Using the techniques available for the SF system, the overall 3M image quality is comparable to that of the SF system, if the exposure is higher (4 to 8 times higher) than the one used for SF system .

LINE PAIR / RESOLUTION PHANTOM

For the test of resolution two different settings were selected, one at 40 kVp and 1.2 mAs, and the other at 50 kVp and 2.5 mAs. In this study the level of noise degrades the lines on the line pair phantom image and causes difficulty for counting the line pair/mm beyond a certain range. The resolutionfor both systems was 6 lp/mm.

As we mentioned previously the 3M system's resolution is comparable to that of the screen-film system.

STEP-WEDGE PHANTOM

In this study, the 14 steps and 10 steps step-wedge phantom tested for two different cases; one at 70 kVp and 2 mAs, and the other at 70 kVp and 10 mAs. This study was done in order to see the dynamic range of the 3M imaging system. The images from the step-wedge phantoms are all included in the extremities examination. By observation, the 3M system has a dynamic range that satisfactorily captures the density of different parts of the anatomy. The claim is that the 3M system has a wider dynamic range compared to the SF system. This claim will be studied later by measuring the optical density of the plate versus a wide range of exposure settings.

4.2 DISCUSSION OF PART II

In part II of the evaluation, a series of exams were performed on the extremities (hand, foot), step-wedge, and line pair / resolution phantoms in order to evaluate the 3M system's performance under optimum condition(s). The optimized base line (accepted image) images are those taken from the conventional SF system. Image processing functions was applied on the 3M images in order to find the preliminary optimum image for comparison with SF images. The 3M images were compared for different kVp, mA, and exposure times as well as dose measurement for anatomy/cassette/imaging plate combination(s).

HAND/CASSETTE/IMAGING PLATE COMBINATION

For the study of hand, the hand phantom/cassette/imaging plate combination was used. The kVp, mA, and exposure time were varied systematically and the skin dose and absorbed dose were measured. This system is shown schematically in Figure 4.1.

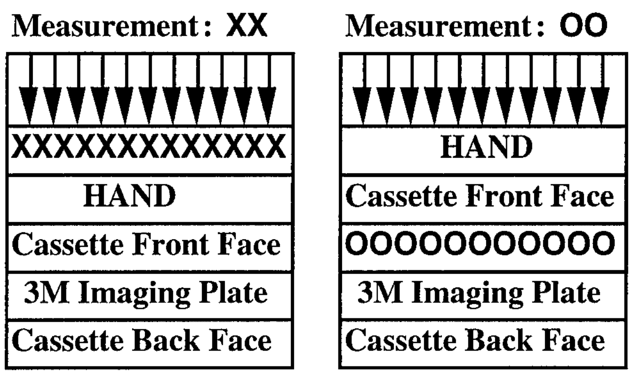

Figure 4.1 Schematic diagram of hand/cassette/imaging plate combinations

As recommended in the first part of this study, we have exposed the system combination systematically by using exposure techniques different than those used for the screen-film system. The results of this study are listed in Tables 4.1, 4.2, and 4.3, for variation of kVp, mA, and exposure time, respectively. At the same time the images are taken on the hard copies without any image processing applied. In all exposures, the resolution phantoms, and the step wedge were used on the side for evaluation of sharpness and the resolution for the 3M system.

Table 4.1 Variation of the absorbed dose by the cassette front face as a function of x-ray tube energy (kVp)

Tube Voltage [kVp]	Exposure at (X) [mR]	Exposure at (O) [mR]	Absorbed Dose Dose [mR]
55	20.4	5.4	15.0
60	25.1	7.1	18.0
65	29.4	8.6	20.8
70	33.3	10.1	23.2

Note that the experiment was done on tabletop with small focal spot size and at a SDD of 40" (102 cm) with fixed mA=250, exposure time=0.02 sec, and mAs=5.

Table 4.2 Variation of the absorbed dose by the cassette front face as a function of x-ray tube current (mA)

Tube Current [mA]	Exposure at (X) [mR]	Exposure at (O) [mR]	Absorbed Dose Dose [mR]	mAs
160	15.0	4.1	10.9	3.2
200	19.4	5.4	14.0	4.0
250	21.5	6.5	15.0	5.0
320	27.8	7.3	20.5	6.4

Note that the experiment was done on tabletop with small focal spot size and at a SDD of 40" (102 cm) with fixed kVp=60 and exposure time=0.02 sec.

Table 4.3 Variation of the absorbed dose by the cassette front face as a function of exposure time (sec.).

Exposure Time [msec]	Exposure at (X) [mR]	Exposure at (O) [mR]	Absorbed Dose Dose [mR]	mAs
12.5	15.4			3.2
16.0	20.1			4.0
20.0	25.1			5.0
25.0	32.0			6.4
32.0	40.8			8.0

Note that the experiment was done on tabletop with small focal spot size and at a SDD of 40" (102 cm) with fixed kVp=60 and mA=250.

By observing the images (Table 4.1), we conclude that a higher kVp will allow for better contrast than expected, but will simultaneously sacrifice the soft tissue and saturate the image. On the other hand the system has the potential of operating in the lower kVp range with lower exposure dose, but losing the bone's fine detail and creating more noise into the image at the same time. This problem can be partially resolved by applying image processing to the image. The system will perform at a level between 5 to 5.6 lp/mm.

In the second series of images (Table 4.2), we do not gain much by raising mAs except for an increase in the exposure dose. The soft tissue looks the same in almost all mAs. The fine details in bone are enhanced at a higher mAs, but the improvement is not significant. The resolution of 5 to 5.6 can be achieved in almost all mAs ranges.

These experiments show that the 3M system has the potential of operating in the lower exposure range with fairly good image quality compared to the screen-film system. The noise in the images is still not resolved but it is improved.

FOOT/CASSETTE/IMAGING PLATE COMBINATION

For the foot study, a similar combination of foot phantomcassette/plate was used. The kVp, mA, and exposure time were varied systematically and the skin dose and absorbed dose were measured. This system is shown schematically in Figure 4.2.

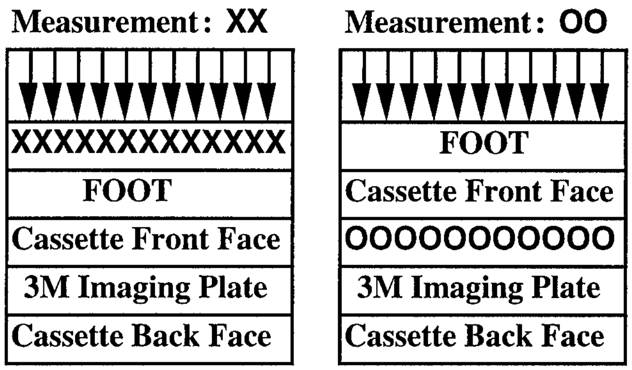

Figure 4.2 Schematic diagram of foot/cassette/imaging plate combinations

Similar to the hand experiment, the foot/phantom/cassette/plate system combination was exposed to x-ray with different exposure techniques. The focus was to find the optimum technique(s) for the 3M imaging system. The results of this study are listed in Tables 4.4, 4.5, and 4.6, for different kVp, mA, and exposure time, respectively. The exposure doses (mR) are measured at different layers of the combination. The images are taken on hard copies without image processing. For all exposures, the resolution phantoms, and the step wedge were used with the anatomy for the evaluation of the system's sharpness and the resolution.

Table 4.4 Variation of the absorbed dose by the cassette front face as a function of x-ray tube energy (kVp)

Tube Voltage [kVp]	**Exposure at (X) [mR]**	**Exposure at (O) [mR]**	**Absorbed Dose Dose [mR]**
55	17.9	2.5	15.2
60	23.8	3.6	20.2
63	26.4	4.3	22.1
65	27.5	4.5	23.0
70	31.4	5.4	26.0

Note that the experiment was done on tabletop with small focal spot size and at a SDD of 40" (102 cm) with fixed mA=250, exposure time=0.02 sec, and mAs=5.

Table 4.5 Variation of the absorbed dose by the cassette front face as a function of x-ray tube current (mA)

Tube Current [mA]	Exposure at (X) [mR]	Exposure at (O) [mR]	Absorbed Dose Dose [mR]	mAs
160	15.7	2.4	13.3	3.2
200	19.9	3.1	16.8	4.0
250	26.4	4.3	22.1	5.0
320	29.4	4.5	24.9	6.4

Note that the experiment was done on tabletop with small focal spot size and at a SDD of 40" (102 cm) with fixed kVp=63 and exposure time=0.02 sec.

Table 4.6 Variation of the absorbed dose by the cassette front face as a function of exposure time (sec.)

Exposure Time [msec]	Exposure at (X) [mR]	Exposure at (O) [mR]	Absorbed Dose Dose [mR]	mAs
12.5	16.1	2.3	13.8	3.2
16.0	20.9	3.3	17.6	4.0
25.0	33.0	5.3	27.7	6.4
32.0	42.6	6.9	35.7	8.0

Note that the experiment was done on tabletop with small focal spot size and at a SDD of 40" (102 cm) with fixed kVp=63 and mA=250.

In the foot/cassette/imaging plate combination experiment similar observation is seen for the variation of kVp. (Refers to Table 4.4, we systematically varied the kVp to 55, 60, 63, 65, and 70 for fixed mA=250, and exposure time=0.02 sec, then printed the images). The images have better contrast at higher kVp with good bone's fine detail, however, the soft tissue in the image are lost. The system is also capable of operating at a lower kVp with fixed mAs. The image resolution is between 5 to 6.3 lp/mm.

In order to study the effect of mA on optimum image quality, a series of experiments were performed by varying mA and printing them on hard copies. For fixed kVp=63, and varying mAs to 3.2, 4.0, 5.0, and 6.4, the soft tissues are more observable from lower mAs to higher mAs, respectively. The heel section of the foot phantom is underexposed and the bone detail is not clear. The image quality of the thicker part of the foot improved significantly.

Noise reduction can be achieved on the foot exam through image processing. In this study the elimination of complete noise also eliminates the fine structure of the foot. We observed that the noise is more visible on the darker side of the image. Limited image processing and elimination of pattern noise will produce better image quality.

LINE PAIR / RESOLUTION PHANTOM

For the test of resolution two different resolution phantoms were selected. They were considered on the side as part of the anatomy images. In this study the level of noise degrades the lines on the line pair phantom image and causes difficulty for counting the line pair/mm beyond a certain range. For this study we observed between 5 to 5.6 lp/mm. As we mentioned previously the system has a good resolution.

STEP-WEDGE PHANTOM

For this study we exposed the step-wedge phantom at the same setting for the anatomy/cassette/imaging plate combination. This study was done in order to see the dynamic range of the 3M imaging system. The images from the step-wedge phantoms are all included in the extremities exams. By observation, the 3M system has enough dynamic range to capture the density of different parts of the anatomy. The wide dynamic range will make the 3M system a promising technology for the future in comparison to the screen-film system.

5.0 CONCLUSIONS

In the evaluation of the 3M digital mammography based on a novel photo-conductor sensor, the feasibility of the system was studied. The focus was on the imaging of body parts (e.g., extremities) less radio-sensitive than breast. This test was necessary before conducting the evaluation in the mammography environment. The system was evaluated in two parts: (1) system performance in high kVp, and (2) system optimization. The tests include the imaging at different exposures and kVp in order to optimize the system performance on image quality. The conclusions are given for the two parts of this study as follows.

5.1 CONCLUSIONS OF PART I

In the first part of the evaluation of the 3M imaging system, the focus was on the images of extremities, hip, and shoulder. The system performance was studied and the conclusions and recommendations were made as follows:

a- Noise is the major problem at this time for the 3M imaging system and must be reduced before the system goes to clinical trial.

b- The 3M system needs to be optimized for kVp, mAs, charged voltage, and read-out voltage

in order to get images comparable to the SF system.

c- Dosimetry is needed to measure the mR amount in the different portions of hip and shoulder. This test will show to a certain extent the radiation dose that will be absorbed by the anatomy and the amount that reaches the plate.

d- We should try to see how much will be gained from image processing.

e- What are the characteristics of the noise? The types of noise influencing the 3M images can result from quantum noise (quantum noise and light photon noise) and fixed noise (structure noise, electronic noise, quantization noise, and other noises).

f- It is important to expose some available mammography phantoms to test the 3M system. This can be done using CD MAM, ACR, and CIRS mammography phantoms for the energy range of 25-35 kVp. This will show us the capability of the 3M system for the lower energy range such as mammography.

5.2 CONCLUSIONS OF PART II

In this phase of study, the system optimization was conducted. In this part of study and after a series of extensive experiments on 3M imaging system, we came to the following conclusions and recommendations for the next phase.

a- The 3M imaging system has shown the capability of operating in the lower kVp with lower exposure dose as compared to the screen-film system without doing any image processing.

b- The variation of mA in the applicable range of radiography has little effect on the foot and hand images.

c- Noise is still a problem at this time and must be reduced. This hopefully will be done in the next phase of the evaluation.

d- The hand images show that the system can be operated in some optimized condition such as at 55 kVp, 250 mA, 0.02 sec, and 5 mAs or 55 to 60 kVp and 3.2 mAs. The 3M system requires mathematical optimization to insure performance comparable to that of the screen-film system.

e- The standard exposure technique system is capable of producing better images for thin parts of the anatomy than the thick parts. To get better resolution and better contrast for thick body parts, the 3M system needs to operate at a higher exposure dose than that of the conventional technique. Hopefully the dose can be reduced through mathematical image optimization and image processing.

f- Dosimetry was used to measure the amount of exposure (mR) in the different portions of the anatomy/cassette/imaging plate combination. The experiments have shown to a certain extent how much of the radiation dose will be absorbed by the anatomy, how much will be absorbed by the cassette front face, and how much will reach the imaging plate

g- We still need to determine what or how much will be gained from image processing. In this study some other filtration is needed and more focus should be spent on contrast enhancement.

h- Using the step-wedge images, the optical density of different steps should be measured. Then a similar H & D curve (for SF system) should be plotted for the 3M imaging system for comparison. This test will show the dynamic range of the two systems. This experiment will be done in the next phase.

i- The physical characteristics of the system will be measured. This includes physics experiments to measure the physical characteristics of the system (MTF, NPS, and DQE).

The radiation exposure necessary was twice that of the screen-film system, and patterned noise still occurred in the images. However, as a result of product redesign, the amounts of noise and radiation exposure required to produce readable images have progressively decreased. Additional improvements are currently being made by the supplier of the equipment. These improvements include improvement in image quality through image processing, different generation of the imaging plate, and optimum exposure technique(s).

5.3. FUTURE WORK

The 3M system will undergo further testing readjustments. Several technical problems such as noise, dose efficiency, and image processing will be addressed. Once additional improvements are made, a series of retests on physics (geometric) phantoms as well as anthropomorphic phantoms will be conducted in order to measure physical property of the new and improved system. If the images are satisfactory, the clinical protocol will be submitted to the IRB for approval of clinical trial.

6. REFERENCES

1- "Breast cancer: Cancer Facts and Figures," American Cancer Society, 1995.

2- Silverberg, E., and Lubera, J.A., "Cancer Statistics," CA-A Cancer Journal for Clinicians, 83:5, 1988.

3- Peter Pare, J.A., and Fraser, R.G., "Synopsis of Disease of the Chest," W.B. Saunders Company, Philadelphia, 1983.

4- Kopans, D.B., "Breast Imaging," J.B. Lippincott Company, Philadelphia, 1989.

5- Kopans, D., and Plews, D., "Digital Mammography", Presented at the National Cancer Institute Consensus Conference "Breast Imaging; State-of-the-Art and Technologies for the Future", September 4-6, (1991).

6- Hunter, T.B., and Fajardo, L.L., "Digital Genitourinary, Gastrointestinal, and Breast Radiology," in Digital Imaging in Diagnostic Radiology, Newell and Kelsey eds., Churchill Livingstone, New York (1990).

7- Chan, H.P., Vyborny, C.J., MacMahon, H., et al., "Digital mammography: ROC studies of the effect of pixel size and unsharp-mask filtering on the detection of subtle microcalcifications," inInvest Radiol, 22:581, (1987).

8- Oestmann, J.W., Kopans D., Hall, D.A., et al., "A comparison of digitized storage phosphors and conventional mammography in the detection of malignant microcalcifications," in Invest Radiol, 23:725, (1988).

9- Johns, P.C., Yaffe, M.J., "X-ray characterization of normal and neoplastic breast tissues," Med. Phys. 12(1), 32-39, (1985).

10- Maidment, A.D.A, Fahrig, R., and Yaffee, M.J., "Dynamic Range Requirements in Digital Mammography, " Med. Phys. 20:1621, (1993).

11- Korn et. al. US Patent 4,176,275; Nov 27, 1978.

12- Korn, D.M., Johnson, S.P., Nelson, O.L., and Ziegler, R.J.: A method of electronic readout of electrophotographic and electroradiographic images. Journal of Applied Photographic Engineering 4(4): 178-182.